Distributed by:
WATMIND USA™

SpeedySwab™

Rapid **COVID-19** Antigen Self-Test

For Emergency Use Authorization (EUA) only. For In Vitro Diagnostic Use

USER INSTRUCTIONS

Carefully read the instructions below before performing the test. Failure to follow the instructions may result in inaccurate test results.

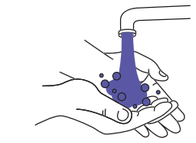
STORAGE AND STABILITY

Store kit between36-86°F (2-30°C). Ensure all test components are at room temperature before use. The Speedy Swab Rapid Covid-19 Antigen Self-Test is stable until the expiration date marked on the outer packaging and containers. Do not use beyond the expiration date. For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

BEFORE GETTING STARTED

1.

Wash or sanitize your hands. Make sure they are dry before proceeding.



2.

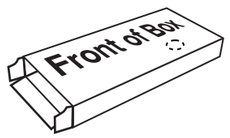
Check the expiration date on the back of the box.

DO NOT use if expired.

PREPARE THE MATERIALS

3.

Bring test to room temperature. On a flat level surface, retrieve all the materials from the box and place the empty box in front of you for further use.



Tests are available in 1, 2, 4, and 25 pack boxes.

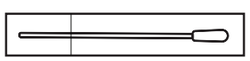
4.

Arrange the materials on a clean, dry, flat surface.

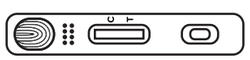
Your box may contain more than one test kit. Use only 1 of each of the materials provided for each test.

DO NOT open the individual pouches until instructed to do so.

MATERIALS PROVIDED:



1x Swab



1x Test Card in Pouch

1x Dropper Top

1x Test Tube

1x Buffer Solution

Timer Not Included

It is recommended that gloves are used during testing. A face mask should be worn if swabbing others. Gloves and face mask are not provided.

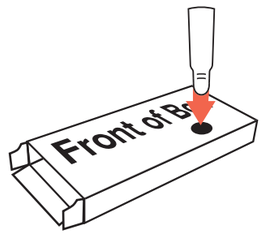
5.

Open large test card pouch and place the test card on flat surface.

DO NOT touch any parts on the insides of the test card.

6.

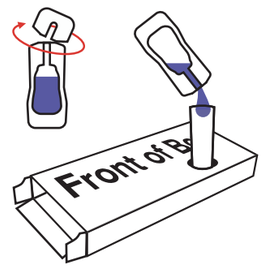
Remove test tube from it's pouch. Press the test tube into the marked hole on the front of the box.



7.

Twist the top off of the buffer solution and pour all of it into the test tube.

If any liquid spills and does not enter into the tube, discard test kit, and re-start test using a new test kit.

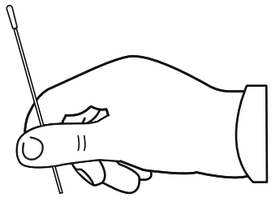


PERFORMING THE TEST

8.

Open swab package from its stick end and remove the swab from this end.

DO NOT touch the swab head.

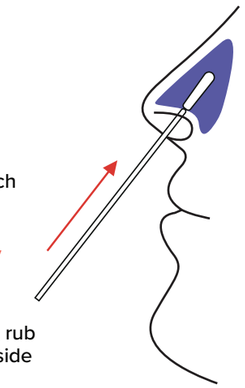


9.

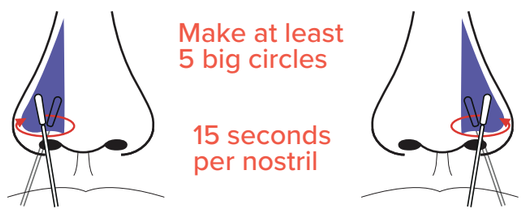
Swab both nostrils carefully with the soft tip as shown.

Step A) Insert 1/2 to 3/4 of an inch

DO NOT insert the swab any farther if you feel any resistance.



Step B) Using medium pressure, rub and rotate the swab against the inside of the first nostril, making at least 5 circles (taking about 15 seconds).



Make at least 5 big circles

15 seconds per nostril

Step C) Repeat in the other nostril.

NOTE: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ of an inch for very young children, you may need another person to steady the child's head while swabbing.

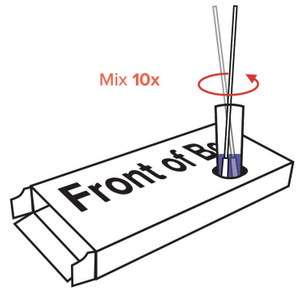
STOP Check: Did you swab BOTH nostrils?

NOTE: inaccurate test results may occur if the nasal sample is not properly collected.

10.

Completely immerse the swab tip in the solution in the tube and mix well by rotating at least 10 times with one hand while holding the box with the other.

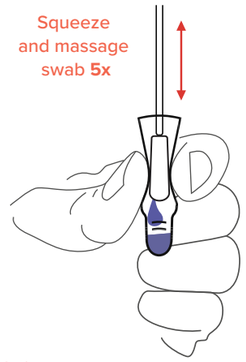
Be sure to mix thoroughly.



11.

While holding the swab stable in the liquid, take the test tube out of the box.

Raise the swab tip out of the buffer, holding it in place within the side walls of the tube, and squeeze the tube **5 times** to remove as much of the liquid from the swab as possible. Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

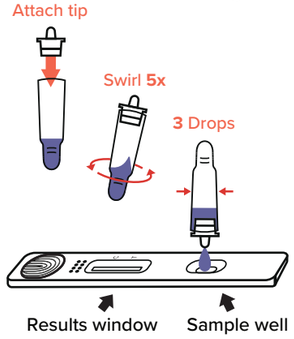


Discard the swab.

12.

Remove dropper tip from it's pouch. Push the dropper tip securely into the tube and swirl 5 times. Turn test tube over, hold it straight up and down, and gently squeeze 3 drops into the sample well on the test card.

DO NOT apply the liquid in the rectangular results window.



13.

Set the timer and read the test result at 15 minutes. (Timer Not Included)

DO NOT disturb the card during this time. Inaccurate results can occur if the card is disturbed/moved or test results are read before 15 minutes.

DO NOT interpret test results after 30 minutes.

NOTE: Inaccurate test interpretations may occur if results are read before 15 minutes or after 30 minutes.

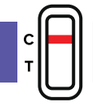
TEST RESULT INTERPRETATION

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

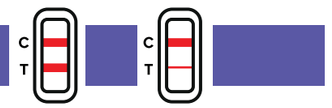
NEGATIVE



If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. **To increase the chance that the negative result for COVID-19 is accurate, you should:**
- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

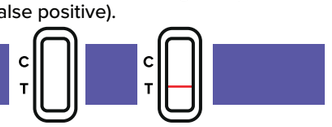
POSITIVE



If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red test (T) line with the control line (C) should be read as positive. **You do not need to perform repeat testing if you have a positive result at any time.**

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/ primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

INVALID



If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

AFTER TEST IS COMPLETED, DISPOSE OF USED MATERIALS IN HOUSEHOLD TRASH.

Report your test result(s) at **www.MakeMyTestCount.Org** – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

Distributed by:

WATMIND USA™

SpeedySwab™

Rapid **COVID-19** Antigen Self-Test

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.

- In Vitro Diagnostic (IVD) use only.
- For Emergency Use Authorization (EUA) only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- For more information on EUAs please visit: https://www.fda.gov-/emergency-preparedness-andresponse/mcm-legal-regulato-ry-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Shenzhen Watmind Medical Co. Ltd
8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community, Kengzisubdistrict, Pingshan District, 518118, Shenzhen, China.
Phone: +86-755-86969964
E-mail: globalbusiness@watmind.com
www.watmind.com

Distribution by :
Watmind USA, Inc.
4780 I 55 N Ste 450
– Jackson, MS 39211 USA
Tel: 1-866-928-6463 (1-866-Watmind)
Email: sales@watmindusa.com
Website: watmindusa.com

INTENDED USE

The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 6 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The Speedy Swab Rapid COVID-19 Antigen Self-Test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the **Speedy Swab Rapid COVID-19 Antigen Self-Test** should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting.

The **Speedy Swab Rapid COVID-19 Antigen Self-Test** is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

HOW TO USE THIS TEST

Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.

If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 6 days you should consider testing at least three times over five days with at least 48 hours between tests.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [e.g., skin, eyes, nose, or mouth]. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your [e.g., e.g., skin, eyes, nose, or mouth], flush with large amounts of water.

If irritation persists, seek medical advice: https://www.poison-help.org or 1-800- 222-1222.

Chemical Name	GHS Code for each Ingredient	Concentrations
Proclin 300	H317, allergic skin reaction	0.1%
Trimethylsilyl acetamide	H316, mild skin irritation	0.03%

- For more information on EUAs please visit: https://www.fda.gov-/emergency- preparedness-and-response/mcm-legal-regulato-ry-and-policy-framework/emergency- use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

FREQUENTLY ASKED QUESTIONS

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

For more information on EUAs go here: https://www.fda.gov/emergen-cypreparedness- and-response/mcm-legal-regulatory-and-poli-cy-framework/emergencyuse-authorization

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the **Speedy Swab Rapid COVID-19 Antigen Self-Test**, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

Q: HOW ACCURATE IS THIS TEST?

A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at WWW.-SpeedySwab.com.

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?

A: A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self isolate from others and contact a healthcare provider for medical advice about your positive result.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?

A: A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARSCoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

A: An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January to June, 2022. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARSCoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

IMPORTANT

This test is intended to be used as an aid in the clinical diagnosis of infection with the virus that causes COVID-19. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

INDEX OF SYMBOLS

	Manufacturer		Date of manufacture
Σ	Contains sufficient for <n> tests	REF	Catalogue number
	Temperature limit	EXP	Use-by date
2	Do not reuse	LOT	Batch code

DOCUMENT VERSION **#33 - 01/23**

TURN OVER

Test Card

WATMIND USA™

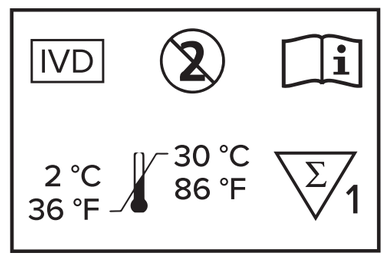
SpeedySwab™

COVID-19 Test Card

EXP YYYYMMDD LOT xxxxxxxxxx

For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

Manufactured for Watmind USA
4780 I 55 N Ste 450 – Jackson, MS 39211 USA
1-866-928-6463 (1-866-Watmind)
Email: sales@watmindusa.com
www.watmindusa.com
Made in China



For symbol glossary, refer to Instructions for Use (IFU).

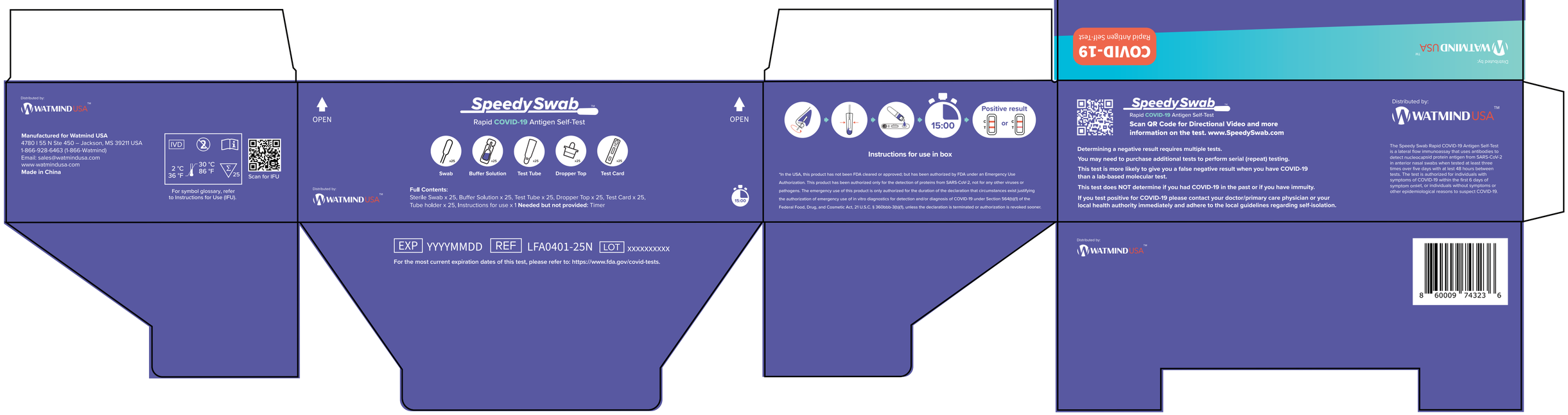
Scan for IFU

1 Test/Box – Outer box

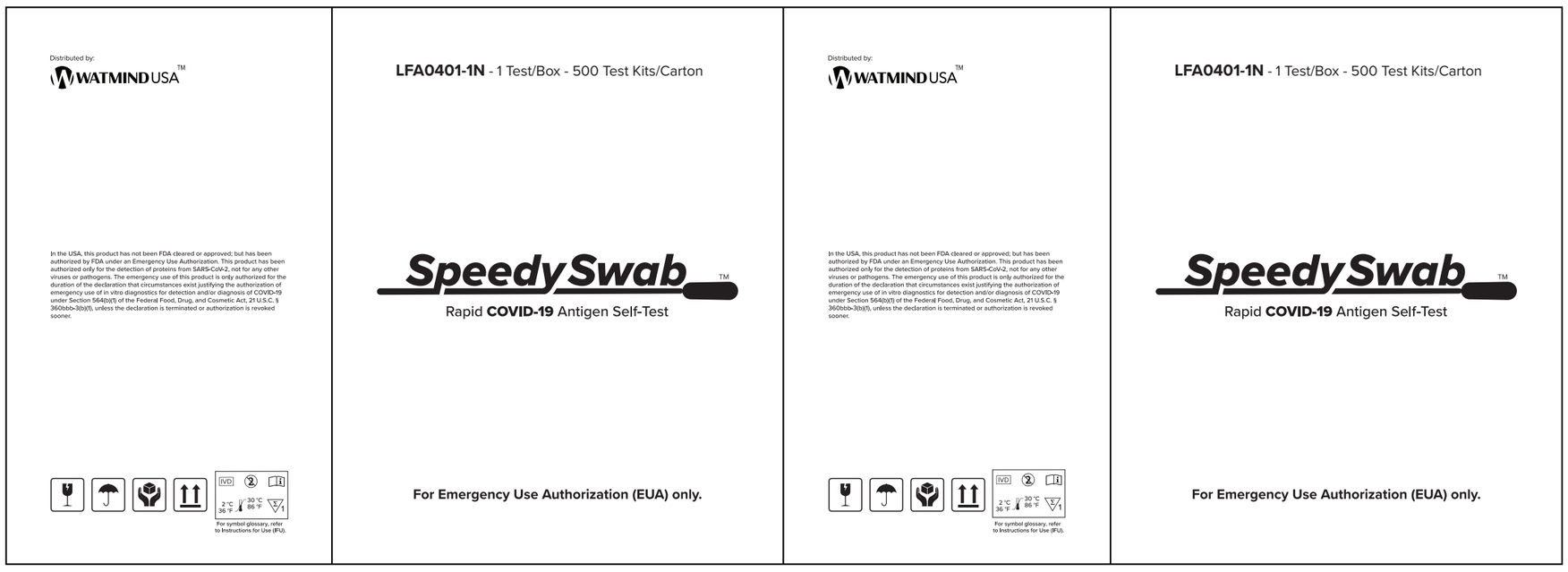
2 Test/Box – Outer box

4 Test/Box – Outer box

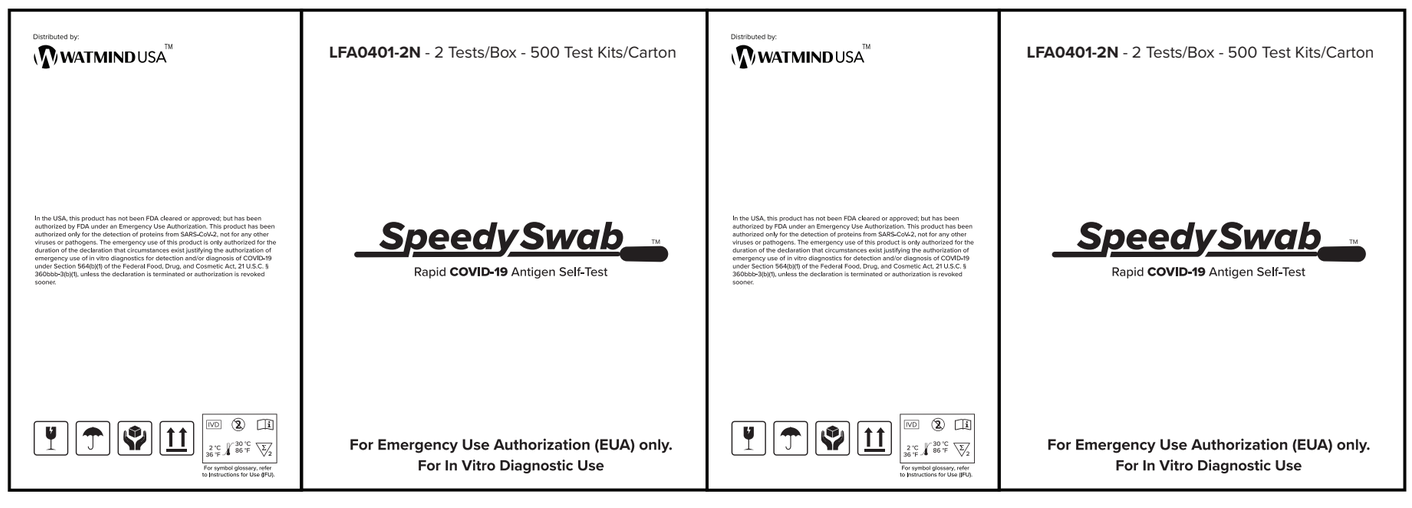
25 Test/Box – Outer box



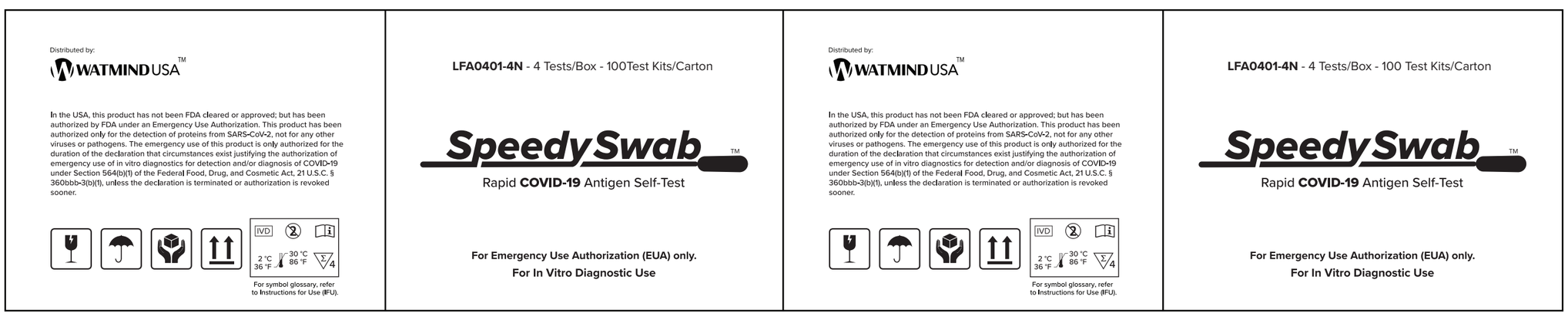
1 Test/Box – Outer box



2 Test/Box – Outer box



4 Test/Box – Outer box



25 Test/Box – Outer box